IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF NEW YORK

GE HEALTHCARE BIO-SCIENCES AB, GE HEALTHCARE BIO-SCIENCES CORPORATION, and GENERAL ELECTRIC COMPANY, Plaintiffs, v. BIO-RAD LABORATORIES, INC., Defendant.	Civil Action No. 14-CV-7080-LTS Hon. Laura Taylor Swain

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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I. INTRODUCTION

Beginning in 2003, Plaintiffs GE Healthcare Bio-Sciences AB's ("Bio-Sciences AB"), GE Healthcare Bio-Sciences Corporation ("Bio-Sciences Corp."), and General Electric Company ("General Electric Co.") (collectively, "GE" or "Plaintiffs") invested enormous resources into developing a next generation state-of-the-art protein purification system that was significantly more flexible, scalable, serviceable, cost-efficient, and user-friendly than prior purification systems. The development presented unique design challenges and required a complete overhaul of both the mechanics and software of GE's existing protein purification systems. The key to such an improved system lay in GE's patented modular design, which allows for interchangeable placement of the fluid handling units and the separation of fluidics and non-fluidics sections.[1] The end result was a flagship system called "ÄKTA avant", designed primarily to meet the needs of biopharmaceutical process development, and a second system, called "ÄKTA pure", designed to meet the needs of academic and industry research customers.

In 2010, Defendant Bio-Rad Laboratories, Inc. ("Bio-Rad") acquired one of GE's flagship modular systems—ÄKTA avant—and hired a former GE employee who was involved in the development of the ÄKTA avant. The reason was simple. Bio-Rad wanted to build a knock-off system that capitalized on GE's years of research and tens of millions of dollars that GE had invested in developing its design. Less than three years later, Bio-Rad announced its own system: the Next-Generation Chromatography ("NGC") system. The ÄKTA and NGC™ preparative protein purification systems are conceptually identical. Both devices are covered by the claims of U.S. Patent No. 8,821,718 entitled "Automated Fluid Handling System" (the

[1] For convenience, this brief uses various shorthand terms such as "modular system", "modular protein purification system", "modular design", and "modular panel design" when referring to GE's patented system.

"'718 patent"), to which Bio-Sciences AB is the sole assignee.[2] GE is entitled to the entry of a preliminary injunction enjoining Bio-Rad from engaging in infringing activities at least because:

- GE is likely to prevail on the merits of the case. There is no real question that Bio-Rad's NGC meets every limitation of independent claims 1 and 16 and dependent claims 2, 3, 5, 11, 14, 17 and 18 of the '718 patent. Further, even Bio-Rad concedes the patentability of GE's modular design in that Bio-Rad itself subsequently filed patent applications covering much of the same subject matter as claimed in the '718 patent.

- GE's modular protein purification business will be irreparably harmed by Bio-Rad's continued infringement. The ÄKTA and NGC systems compete directly. Bio-Rad's ability to copy GE's design means that it did not need to invest nearly the same resources into its development as GE, thereby allowing Bio-Rad to underprice GE and to offer free "add-ons" to customers. This has allowed and will continue to allow Bio-Rad to take customers from GE and to erode GE's pricing structure. Moreover, Bio-Rad's targeting of GE's customers, especially in the academic market, has led and will continue to lead to GE losing sales to Bio-Rad and to a diminishment of GE's reputation and goodwill among customers in the market for preparative protein purification systems.

The balance of hardships and the public interest also weigh heavily in favor of an injunction. Accordingly, pursuant to Federal Rule of Civil Procedure 65(a) and 35 U.S.C. § 283 and as set forth further herein, GE respectfully requests that this Court enter an order enjoining Bio-Rad from making, using, selling or offering for sale its NGC™ Chromatography System, or any other products that are not significantly different therefrom, which infringe the '718 patent.

II. STATEMENT OF FACTS

A. GE and the Patented Technology.

The healthcare business of GE develops and sells life science technologies and services to help scientists and the pharmaceutical industry deliver better and more cost-efficient care to patients worldwide. Sklenar Decl.[3] Ex. A. GE's healthcare business has a well-established

[2] Bio-Sciences AB became part of GE in 2004 and will be referred to herein as GE.

[3] "Sklenar Decl." refers to the Declaration of Jennifer Sklenar in Support of Plaintiffs' Motion for a Preliminary Injunction.

reputation as an innovator in the fields of protein purification and drug discovery (*id.*, Ex. B), and has developed, manufactured, and sold protein purification-related technologies since the 1950s. Darby Decl.[4] ¶ 4.

Protein purification is an important aspect of biopharmaceutical research and manufacturing. *Id.* ¶ 5. Protein purification is, generally speaking, a series of processes intended to isolate a single or small number of proteins from a complex mixture. *Id.* ¶ 5. Such isolation is essential for the characterization of the function, structure, and interactions of proteins of interest (an important step, for example, in developing bio-pharmaceutical drugs used in the treatment of cancer and viral diseases and in developing vaccines). *Id.* ¶ 5. Protein purification can be roughly divided into an analytical and preparative method: the analytical method aims to detect and identify proteins in a mixture, while the preparative method aims to produce large quantities of proteins for purposes such as industrial use and typically involves chromatography. *Id.* ¶ 6.

Preparative protein purification can be accomplished through any number of means, including through a liquid chromatography system. *Id.* ¶ 7. Such a system utilizes pumps to pass a pressurized liquid solvent containing a sample mixture through a column filled with a protein separation substance, for example, a solid adsorbent[5] material. *Id.* ¶ 7. Where adsorbent material is used, each component in the sample interacts slightly differently with the material, causing different flow rates for the different components and leading to the separation of the components as they flow out the column. *Id.* ¶ 7. A typical liquid chromatography system includes an assortment of fluid handling components, such as pumps, valves, mixers, and sensor

[4] "Darby Decl." refers to the Declaration of Nigel Darby in Support of Plaintiffs' Motion for a Preliminary Injunction.

[5] Adsorption, not to be confused with absorption, is, generally speaking, the adhesion of atoms, ions, or molecules from a gas, liquid, or dissolved solid to a surface. Darby Decl. ¶ 7.

units of different types. Sklenar Decl. Ex. C at 1:19-22. These components are interconnected by fluid conduits, such as rigid or flexible tubes or "capillaries". *Id*. Ex. C at 1:22-24.

Although some liquid chromatography systems are designed for a specific type of application with a specific flow path, many researchers need flexibility to alter or optimize the fluid path flow of the system. *Id*. Ex. C at 1:24-26. Historically, upgrading a liquid chromatography system required use of specific kits provided by the manufacturer, and such upgrade kits were often supplied as external add-on equipment to be arranged beside the original system. *Id*. Ex. C at 1:27-30. Thus, upgrades typically required enlarging the footprint of the system with equipment that still needed to be connected to the system both fluidically and electrically. *Id*. Ex. C at 1:30-33. Moreover, replacement of defective fluid handling units was often a time-consuming and delicate task requiring the assistance of specialized service personnel. *Id*. Ex. C at 1:33-35.

Beginning in 2003, GE began developing a modular design for preparative protein purification systems that would enable researchers to more quickly, easily, and cost-effectively purify proteins. Darby Decl. ¶ 9. The basic idea underlying the modular design concept was to organize a complex system as a set of distinct and interchangeable components that could be manufactured independently and then plugged into mating bay positions in the instrument housing. *Id*. ¶ 9. GE believed that such a modular design would not only simplify researchers' work, but also give researchers a flexible option for expanding and tailoring their purification capabilities as the research progresses. *Id*. ¶ 9.

To this end, Johan Blomberg and Mats Lundkvist invented a modular automated fluid handling system for the preparative purification of proteins. Sklenar Decl. Ex. C. On June 9, 2009, they filed a patent application in Sweden and then, on June 4, 2010, they filed a patent

cooperation treaty (PCT) application, which ultimately led to the issuance of the '718 patent on September 2, 2014. *Id*. Ex. C. The '718 patent is generally directed to a highly-flexible and configurable automated fluid handling system, such as a liquid chromatography system. *Id*. Ex. C at 1:14-18. More specifically, the '718 patent recites an automated fluid handling system featuring a housing of interchangeable fluid handling modules, and which includes a fluidics section external to the housing, a non-fluidics section with electrical components internal to the housing, and a panel that separates the two sections and allows the module to be attached to the housing. *See, e.g., id*. Ex. C at claim 1.

The system claimed by the '718 patent has several advantages over the prior art, including (1) increasing the flexibility of the system; (2) making it easier to scale the system without increasing the system's footprint; (3) allowing for easier service of modules by swapping modules needing repair with working modules; (4) allowing for individual manufacture of components; (5) enabling researchers to customize systems to a certain price point and/or functionality, including optimization for various applications; and (6) enabling a system with better ergonomics and a more user-friendly design. *Id*. Ex. C at 1:45-54; Darby Decl. ¶ 9.

B. GE's ÄKTA Systems.

One important line of products developed by GE is its protein purification systems marketed and sold under the trade name ÄKTA™. Two of GE's earliest ÄKTA systems were the ÄKTAexplorer system, launched in 1996, and the ÄKTApurifier system, launched in 1997. Darby Decl. ¶ 8. The quality and reliability of both systems were well-regarded in the preparative protein purification market. *Id*. ¶ 8.

In developing its next generation "modular" design, GE devoted six years and substantial resources into the development of a modular protein purification system in accordance with its goals. *Id*. ¶ 10. The project required a complete overhaul of both software and instruments. To

achieve its goals, GE committed a significant part of its R&D team in Uppsala, Sweden and manufacturing team in Umeå, Sweden, between 200-250 employees, and conducted extensive market research. *Id.* ¶ 10. Development of the new designs cost GE over $100 million. *Id.* ¶ 10.

In August 2009, GE launched its flagship modular preparative protein purification system, the ÄKTA avant system. *Id.* ¶ 11. The ÄKTA avant system is a distinctive modular system that offers a large range of options to allow flexibility in purification of proteins. *Id.* ¶ 11. ÄKTA avant is designed to meet the needs of process developers and can be customized with a number of flexible module options to extend the hardware functionality. *Id.* ¶ 11. Among other things, this system also provides for separation of fluidics sections (external to the housing) from non-fluidics sections (internal to the housing). *Id.* ¶ 11. The ÄKTA avant system currently is available in two versions. *Id.* ¶ 11. ÄKTA avant 25 is optimized for media screening and method optimization using small columns. *Id.* ¶ 11. ÄKTA avant 150 is designed for scaling up to larger columns, as well as fine tuning and robustness testing of the optimized process. *Id.* ¶ 11. At the time of its launch, the ÄKTA avant system was the only chromatography system on the market to offer a modular panel design allowing for interchangeable placement of the fluid handling units and which separated the fluidics section from the non-fluidics section. *Id.* ¶ 11.

In August 2012, GE launched a second modular preparative protein purification system, the ÄKTA pure system. *Id.* ¶ 12. The ÄKTA pure system is a flexible and intuitive chromatography system for fast purification of proteins, peptides, and nucleic acids from microgram to gram levels of target product. *Id.* ¶ 12. The ÄKTA pure system can be tailored to a customer's precise needs through a broad selection of hardware options from valves and tubing to monitors and fraction collectors. *Id.* ¶ 12.

GE's user-friendly modular protein purification systems were groundbreaking when they were first introduced, and have been greeted with considerable praise. *See id.* ¶¶ 11, 13. In fact, when the ÄKTA avant system was first launched in 2009, it was the first chromatography system on the market to offer a flexible modular design that included, for example, an attractive modular panel design allowing for interchangeable placement of the fluid handling units and which separated the fluidics section from the non-fluidics section. *Id.* ¶ 11. Thereafter, GE expended considerable effort and expense to improve upon the design and launched the ÄKTA pure system in 2012. *Id.* ¶ 12. The year after, the ÄKTA pure system was nominated as the best new separations product introduced on the market in 2012 by SelectScience, an independent, expert-led scientific review resource for the worldwide scientific community. *Id.* ¶ 13.

GE also has expended considerable effort and expense to train researchers on the use of modular protein purification systems, and in particular, the use of the ÄKTA avant and ÄKTA pure systems. *Id.* ¶ 14. Specifically, GE's efforts and investments have been directed towards education about the scalability and productivity of the unique design of the ÄKTA avant system, and the flexibility of the intuitive design of the ÄKTA pure system. *Id.* ¶ 14.

C. Bio-Rad's Development and Marketing of the NGC System.

In January 2013, Bio-Rad began marketing and selling a modular protein purification system under the brand name NGC™. *Id.* ¶ 18. Rather than develop its own modular system, however, Bio-Rad decided to copy GE's concept of modular protein purification technology.

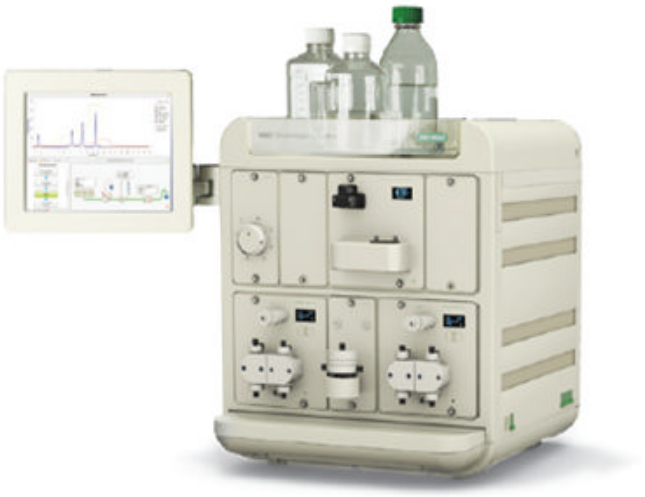
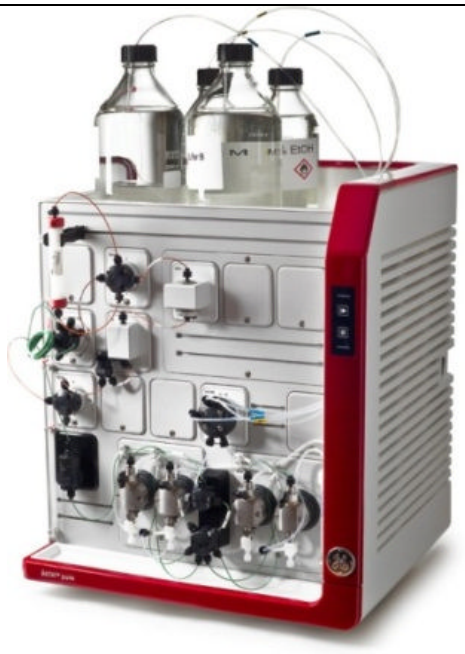
In 2010, Bio-Rad hired one of GE's former employees to work as a senior product managers for its "Next Gen Chromatography" project. *Id.* ¶ 16; Sklenar Decl. Ex. D. Previously, from about 2000 to 2008, this employee had been employed as a senior account manager at GE, during which time he gained insight into the development and launch strategy of

the new generation of ÄKTA modular protein purification systems, having been a member of the products' concept teams. Darby Decl. ¶ 16.

That same year, in March 2010, Bio-Rad purchased an ÄKTA avant system (*id*. ¶ 15) under the pretense that it was being used to support protein process development when, in fact, Bio-Rad wanted to build a knock-off system. Bio-Rad's true intent was confirmed on October 26, 2012, when Bio-Rad employee Paul Johnson emailed GE employee Vivan Tseng, with a cc to Bio-Rad employees Michael Urban and Richard Lee, requesting an upgrade for the ÄKTA avant system that Bio-Rad had purchased. *Id*. ¶ 17 and Ex. A. Each of Messrs. Johnson, Urban and Lee were involved in Bio-Rad's "Next Gen Chromatography" project. Sklenar Decl. Exs. E, F, and G. Mr. Urban "replied to all," stating in his reply email that he was "very skeptical that [Mr. Johnson] will get much traction with [Ms. Tseng] with [his] email signature indicating [he is] a lab chromatography marketing specialist. Darby Decl. ¶ 17 and Ex. A. Mr. Urban went on to state that Bio-Rad purchased the ÄKTA avant system "under the pretense that it was being used to support protein process development." *Id*. ¶ 17 and Ex. A. Mr. Urban further stated that he "would like to keep the story going so that we could service on our akta when needed." *Id*. ¶ 17 and Ex. A.

Bio-Rad's NGC system is a modular system that provides a controlled fluid flow through a chromatography column for the purpose of preparative protein purification. Scandella Decl.[6] ¶ 67 & Ex. C pp. 9, 23-24, 26. Although early renderings of the NGC system appear to have been modeled off of the ÄKTA avant system (compare Sklenar Decl. Ex. H with Ex. I), the final product bears a striking resemblance to GE's ÄKTA pure system:

[6] "Scandella Decl." refers to the Declaration of Carl Scandella, Ph.D.

Bio-Rad's NGC system	GE's ÄKTA pure system
	

Like the ÄKTA pure system, the NGC system consists of a housing that features a front panel with multiple openings, each opening constructed to allow the bay behind the opening to receive various types of fluid handling modules, such as valves, pumps, sensors, and mixers. Scandella Decl. ¶¶ 31-32, 79-80, 97 & Ex. C at pp. 19-76, 187-90. The modules of the NGC system come in one of two sizes: single or double; a single receiving bay can receive any single module, or any two adjacent single receiving bays can be combined to receive any double module. *Id.* ¶ 44 & Ex. C at pp. 188-89. Each module contains a face panel that enables the module to be secured to the front panel of the NGC system, and which separates the external fluidics section of the module from its internal, non-fluidics section. *Id.* ¶ 41 & Ex. C at pp. 19-74, 186, 188. Each face panel of the module is provided with a sealing member to provide a sealed attachment of the module to the front panel of the NGC system. *Id.* ¶ 50 & Ex. C at pp. 19-74, 186. The non-

fluidics section includes various electronics and electrical components. *Id*. ¶¶ 39, 87 & Ex. C at pp. 188-89.

Bio-Rad touts "the uniform, evenly divided front face" of the modular design as being the "most striking aspect" of the NGC system. Sklenar Decl. Ex. J. Bio-Rad also markets the modular design as being highly flexible, and scalable, and adaptable to the needs of researchers. As Bio-Rad explains, for example, "[b]eing able to change one module at a time lets the instrument grow in line with purification needs…. The user can also configure and build her own chromatography system by adding the permutations and combinations that suit her own individual needs." *Id*. Ex. J. Bio-Rad also advertises the service-related benefits of the modular design: "Swapping modules in this way has another benefit: should a given device requires [*sic*] service, it's simple to remove it, mail it to Bio-Rad, and replace it. This keeps any one part from shutting down an entire system." *Id*. Ex. J. The modular design is also convenient to use: "Modules are 'plug and play,' locking into place and automatically registering on the system's…software." *Id*. Ex. J.

Since its launch, Bio-Rad has continued to market, promote, and sell the NGC system, including to accounts that presently use ÄKTA systems. Darby Decl. ¶ 20. In its marketing campaign, Bio-Rad targeted GE's ÄKTA systems in a series of videos uploaded to YouTube. *Id*. ¶ 20.

In 2011, Bio-Rad applied for at least two U.S. patent applications on its NGC system. Sklenar Decl. Exs. K and L. Bio-Rad's applications overlap significantly with the '718 patent by attempting to claim, for example, "[a] system for joining a plurality of fluid manipulation components into a flow scheme for directing fluids to and from a chromatographic separation device and for operating said flow scheme according to a selected protocol," where such system

comprises: (a) a plurality of modules of fluid manipulation components and a microcontroller; (b) a mounting frame with a plurality of mounting sites; and (c) programmable software that communicates with the microcontroller of each module. *Id.* Ex. K.

D. Harm Suffered By GE As The Result Of Bio-Rad's Infringement.

GE was the first company to offer, make, and sell a modular preparative protein purification system that included, for example, a modular panel design allowing for interchangeable placement of the fluid handling units and which separated the fluidics section from the non-fluidics section. Darby Decl. ¶ 11. By being first, the company—at least temporarily—enjoyed the freedom to market its offering in the absence of substitutes. *Id.* ¶ 11.

GE and Bio-Rad are direct competitors. *Id.* ¶ 21. The ÄKTA pure and NGC systems are the only modular preparative protein purification systems that feature the modular panel design allowing for easy swapping of interchangeable modules. *Id.* ¶ 21. Regardless of any purported difference between the systems as advertised by the parties, both systems address the same segment of the market.

Bio-Rad's blatant copying of the ÄKTA avant and ÄKTA pure systems and aggressive targeting of GE's customers has caused GE to lose sales of its ÄKTA systems to Bio-Rad's NGC system. Bio-Rad has sold a substantial number units of the NGC system worldwide covering a significant number of different customers. *Id.* ¶ 22. In most of these instances, GE lost a sale of an ÄKTA pure system. *Id.* ¶ 22. For example, GE has lost sales of the ÄKTA pure system to Bio-Rad's NGC system to Drexel University, Georgia State University, University of California at Berkeley, University of Illinois, Cornell University, Case Western Reserve University, University of Iowa, Medical College of Wisconsin, and University of Georgia. *Id.* ¶ 22. Many of these lost sales are the result of Bio-Rad pricing its NGC system lower than the ÄKTA pure system. *Id.* ¶ 22.

Additionally, Bio-Rad's aggressive pricing of the NGC system and related products and services threatens to erode GE's pricing of its ÄKTA systems. Bio-Rad regularly offers free or discounted "add-ons" to attract customers, such as a free second year warranty and free or discounted software. *Id.* ¶ 22. Indeed, Bio-Rad's pricing structure and free "add-ons" have eroded GE's pricing of its ÄKTA pure system.

GE had begun to see a return on its investment prior to the launch of the Bio-Rad NGC system, as acceptance of the design has increased in the preparative protein purification market, and as sales began to grow. *Id.* ¶ 27. However, Bio-Rad's introduction of the NGC system has caused GE to lose sales. *Id.* ¶¶ 22, 27. If Bio-Rad is allowed to continue its sales of the NGC system, GE believes it will continue to lose sales and that it will suffer further price erosion of its ÄKTA systems. *Id.* ¶ 27.

In addition to lost sales and eroded prices, Bio-Rad's manufacture, sale and use of its modular design threatens GE's future growth. First, the continued presence of the NGC system in the market will prevent GE from gaining the first mover advantage that it needs, especially to strengthen its presence in the academic market. *Id.* ¶ 24. Additionally, the disruption caused to researchers in the event that they purchase the NGC system only to have to remove it as a result of a permanent injunction upon the finding of infringement in this case could irreparably harm GE's goodwill (*id.* ¶ 25) in ways that are incalculable as a matter of patent damages.

III. LEGAL STANDARDS GOVERNING PRELIMINARY INJUNCTIONS

The Patent Act provides that a district court "may grant injunctions in accordance with principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. "It is well settled that the granting of a temporary injunction, pending final hearing, is within the sound discretion of the trial court…." *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1345 (Fed. Cir. 2008) (citing *Deckert v. Independence*

Shares Corp., 311 U.S. 282, 290 (1940)). Although it is an extraordinary remedy, the courts have recognized that the "the purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Id.* at 1344-45 (citing *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981)).

"The factors the trial court considers when determining whether to grant a preliminary injunction are of longstanding and universal applicability. As the Supreme Court recently reiterated, there are four: '[a] plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of the equities tips in his favor, and [4] that an injunction is in the public interest.'" *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375-76 (Fed. Cir. 2009) (quoting *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). "These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of relief requested." *Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988).

IV. ARGUMENT

A. <u>It Is Highly Likely That GE Will Prevail On The Merits Of Its Case.</u>

In order to establish a likelihood of success on the merits "the patentee must demonstrate that it will likely prove infringement of one or more claims of the patents-in-suit, and that at least one of those same allegedly infringed claims will also likely withstand the validity challenges presented by the accused infringer." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001). "In assessing whether the patentee is entitled to the injunction, the court views the matter in light of the burdens and presumptions that will inhere at trial." *Titan Tire*, 566 F.3d at 1376.

1. Bio-Rad Infringes the '718 Patent.

A patent owner has the burden of proving infringement, and must meet that burden by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Lab. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). "An infringement analysis proceeds first to claim construction to determine the scope and meaning of the asserted claims, and second to a comparison of the properly construed claims with the allegedly infringing product to determine whether the product embodies every limitation of the claims." *Biagro Western Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1301 (Fed. Cir. 2005). As set in further detail below and in the concurrently-filed declaration of Carl Scandella, Ph.D., the evidence in this case plainly establishes that the Bio-Rad's NGC system infringes claims 1, 2, 3, 5, 11, 14, 16, 17, and 18 of the '718 patent.[7]

a. Claim Construction

Claim construction begins with the words of the claims, which "are generally given their ordinary and customary meaning." *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Indeed, there is "a 'heavy presumption' that a claim term carries its ordinary and customary meaning." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). The Federal Circuit has explained "that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1313.

Here, none of the asserted claims of the '718 patent appear to contain any language that requires special construction at this time. The ordinary meaning of each claim term is "readily

[7] For purposes of this motion, GE only addresses Bio-Rad's infringement of independent claims 1 and 16 and dependent claims 2, 3, 5, 11, 14, 17, and 18 of the '718 patent. GE does not waive its claims for infringement of the other claims of the '718 patent.

apparent," and thus claim construction in this matter "involves little more than the application of the widely accepted meaning of commonly understood words." *Id*. at 1314.

b. The Bio-Rad NGC System Directly Infringes Claims 1, 2, 3, 5, 11, 14, 16, 17, and 18 of the '718 Patent.

Based upon the plain meaning of the asserted claims, Bio-Rad's manufacture, sale, and use of the NGC system directly infringes independent claims 1 and 16 and dependent claims 2, 3, 5, 11, 14, 17, and 18 of the '718 patent. Bio-Rad has sold the NGC system since at least January 2013. *See supra* at Section II.C. Further, as shown in the accompanying testimony of Dr. Carl Scandella, the NGC system literally meets each and every limitation of the asserted claims. Scandella Decl. Section VII.

2. There Is No Substantial Question About Validity Of The '718 Patent.

"[A] patent enjoys the same presumption of validity during preliminary injunction proceedings as at other stages of litigation. […] Thus, if a patentee moves for a preliminary injunction and the alleged infringer does not challenge validity, the very existence of the patent with its concomitant presumption of validity satisfies the patentee's burden of showing a likelihood of success on the validity issue." *Titan Tire*, 566 F.3d at 1377 (internal citations omitted); *see also* 35 U.S.C. § 282.

Bio-Rad has the burden "to come forward with evidence of invalidity." *Titan Tire*, 566 F.3d at 1377. Given the several-year examination period of the '718 patent application in the PTO, it is unlikely that Bio-Rad will present prior art references that are more relevant than those already considered by the patent examiner in ultimately determining that the claimed subject matter was patentable. Moreover, Bio-Rad itself has already acknowledged the patentability of the subject matter covered by the '718 patent. In 2011, Bio-Rad filed at least two applications for U.S. patents covering the same modular aspects of their NGC system. Sklenar Decl. Exs. K

and L. These applications described the patentable invention as being, for example, "[a] system for joining a plurality of fluid manipulation components into a flow scheme for directing fluids to and from a chromatographic separation device and for operating said flow scheme according to a selected protocol," where such system comprises: (a) a plurality of modules of fluid manipulation components and a microcontroller; (b) a mounting frame with a plurality of mounting sites; and (c) programmable software that communicates with the microcontroller of each module. *Id*. Ex. K.

B. GE Will Be Irreparably Harmed By Bio-Rad's Continued Infringement.

For at least the following reasons, Bio-Rad has harmed and continues to irreparably harm GE by making, marketing, and selling its NGC system.

First, "[w]here failure to grant an injunction would allow a competitor to enter the market, district courts have continued to issue injunctions." *Amgen, Inc. v. F. Hoffman-La Roche, Ltd.*, 581 F. Supp.2d 160 (D. Mass. 2008), aff'd in part, vacated in part on other grounds, remanded sub nom. *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009). *See Tactica Int'l, Inc. v. Atl. Horizon Int'l, Inc.*, 154 F. Supp. 2d 586, 603 (S.D.N.Y. 2001) (preliminarily enjoining defendant from infringing upon plaintiff's trademark, trade dress, and/or patent rights in the sale, distribution, or advertising of its products where "[t]here is no doubt that [plaintiff] and [defendant] would compete directly against each other in the same market"); *Sanofi-Synthelabo v. Apotex Inc.*, 492 F. Supp. 2d 353, 356 (S.D.N.Y. 2007) aff'd, 550 F.3d 1075 (Fed. Cir. 2008) (granting preliminary injunction to "Sanofi—which invested in the research and development to patent and bring to market the drug known as Plavix®—and Apotex, which seeks to market the generic equivalent of that drug"). Numerous courts have found irreparable harm "under circumstances where [the] plaintiff practices its invention and is a direct market competitor" of the defendant's. *Becton Dickinson and Co. v. Tyco Healthcare*

Group LP, No. 02-1694GMG, 2008 U.S. Dist. LEXIS 87623, at *9 (D. Del., Oct. 29, 2008) (quotation omitted); *see also Mass Engineered Design, Inc. v. Ergotron, Inc.*, 633 F. Supp. 2d 361, 393 (E.D. Tex. 2009) ("direct competition in a marketplace weighs heavily in favor of a finding of irreparable injury"). Here, GE and Bio-Rad are not only direct competitors, they are the two primary competitors in the relevant market – modular preparative protein purification systems. *See supra* at Section II.D. According to the Federal Circuit, "the existence of a two-player market may well serve as a substantial ground for *granting* an injunction – e.g. because it creates an inference that an infringing sale amounts to a lost sale for the patentee." *Robert Bosch LLC v. Pylon Mfg Corp.*, 659 F.3d 1142, 1152 (Fed. Cir. 2011). Therefore, the harm to GE is irreparable because the vast majority of NGC system sales by Bio-Rad are to the exclusion of GE sales. *See supra* at Section II.D.

Second, by selling modular preparative protein purification systems, Bio-Rad is curtailing GE's ability to market the use of its ÄKTA systems as a unique innovation. Being an innovator in the protein purification industry is highly advantageous. For example, by being first to the market with this technology, GE should have enjoyed the freedom to market and sell its ÄKTA systems in absence of substitutes. *See supra* at Section II.B. For this reason, courts have recognized that "where a company pioneers an invention in the marketplace, irreparable harm flows from a competitor's attempts to usurp the pioneering company's market position and goodwill." *See 800 Adept, Inc. v. Murex Sec., Ltd.*, 505 F. Supp. 2d 1327, 1337 (M.D. Fl. 2007), aff'd in part, vacated in part and rev'd in part on other grounds, 539 F.3d 1354 (Fed. Cir. 2008); *Hutzler Mfg. Co. v. Bradshaw Int'l, Inc.*, 11 CIV. 7211 PGG, 2012 WL 3031150 at *17 (S.D.N.Y. July 25, 2012) ("[T]he potential loss of…the advantage of being the pioneer in the

field and the market leader [ ] may constitute irreparable harm.") (internal quotations and citations omitted).

Furthermore, each sale lost to Bio-Rad's NGC system causes further irreparable harm to GE in the form of lost future sales opportunities. With each sale of its NGC system, Bio-Rad is generating a deeper relationship with its customer and gains the ability to market additional products to existing customers. *See supra* at pp. 9-10. In fact, Bio-Rad already has a suite of complementary offerings (*e.g.*, chromatography columns and instrument repair services), which compete with GE's complementary offerings, that Bio-Rad markets and sells with the NGC System to the same customers, giving it yet another competitive advantage over GE. Darby Decl. ¶ 27. Consequently, Bio-Rad's infringement does not only inflict immediate loss in sales and profits on GE. It also is reshaping the market in ways that will inflict continued long-term irreparable harm. *See, e.g.*, *TiVo, Inc. v. Echostar Commn's Corp.*, 446 F. Supp. 2d 664, 670 (E.D. Tex. 2006) rev'd on other grounds, 516 F.3d 1290 (Fed. Cir. 2008) ("[T]he impact of Defendants' continued infringement is shaping the market to Plaintiff's disadvantage and results in long-term customer loss."); *see also Mister Softee, Inc. v. Tsirkos*, No. 14 CIV. 1975 LTS RLE, 2014 WL 2535114 at *10 (S.D.N.Y. June 5, 2014) (Swain, J.) (granting preliminary injunction where "[p]laintiffs have made a clear showing that they will suffer irreparable harm in the form of customer confusion, loss of good will, and potential damage to their reputation if Defendant is allowed to continue" to infringe plaintiffs' trademarks).

Third, if Bio-Rad's sales of the NGC system are not preliminarily enjoined in this action, GE will likely experience lost goodwill when GE succeeds in proving infringement and the NGC system is removed from the market. Both GE and Bio-Rad engage in training and education as part of their sales process, thus creating brand loyalty. The loyalty created by Bio-Rad during

the pendency of this lawsuit, if it were permitted to continue selling the NGC system, may result in academic institutions and other research and development centers that are reluctant to switch from the NGC system to the ÄKTA system when GE obtains a permanent injunction. Thus, the more time Bio-Rad is allowed to infringe, the more researchers will begin using the NGC system, resulting in more harm to GE.

C. The Balance Of Hardships Weighs Heavily In Favor Of An Injunction.

For all the reasons discussed above in connection with the irreparable harm factor, the balance of the hardships strongly favors granting an injunction. *See supra* Section II.D. The hardship imposed on GE as the result of Bio-Rad's infringing conduct is substantial. *See Bosch*, 659 F.3d at 1156 (requiring a patentee to compete against its own patented invention, with the resultant harms—*e.g.*, loss of market share, loss of access to potential customers, and price erosion—"places a substantial hardship" on the patentee); *Canon Inc. v. GCC Int'l Ltd.*, 450 F. Supp. 2d 243, 256-57 (S.D.N.Y. 2006) aff'd, 263 F. App'x 57 (Fed. Cir. 2008) (where patentee suffered "loss of profits and market share" as a result of competitor's infringement, the "balance of hardships tips decidedly in plaintiff's favor"). As discussed above, GE invested six years and significant resources in developing the technology necessary to support a modular design for a preparative protein purification system. This required a significant part of GE's Uppsala R&D team and more than $100 million. *See supra* Section II.B; *Edwards Lifesciences AG v. CoreValve, Inc.*, No. CV 08-91 (GMS), 2014 WL 1493187 at *8 (D. Del. Apr. 15, 2014) (granting preliminary injunction to patentee who argued that "the public interest weighs in its favor because of the policy inherent in the patent laws protecting a patentee's investment in research and development through exclusive patent rights"); *Med. Econ. Co. v. Prescribing Reference, Inc.*, 294 F. Supp. 2d 456, 462 (S.D.N.Y. 2003) (where plaintiffs "invested considerable advertising and other resources in releasing their [product]…the balance of

hardships tips in [their] favor."); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (affirming district court's grant of preliminary injunction and finding that public interest favored encouragement of the plaintiff's patent because "encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude").

In contrast, Bio-Rad will suffer little if no harm if the Court issues an injunction. The Federal Circuit has long held that "[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." *Windsurfing Int'l, Inc. v. AMF, Inc*. 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986). Bio-Rad cannot rely upon any alleged loss of market share or customer relationships, because "[s]imply put, an alleged infringer's loss of market share and customer relationships, without more, does not rise to the level necessary to overcome the loss of exclusivity experienced by a patent owner due to infringing conduct." *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005). Additionally, the nature of Bio-Rad's business is to sell "a broad range of innovative tools and services to the life science research and clinical diagnostics markets." *See* Sklenar Decl. Ex. M. Bio-Rad sells more than 8,000 products, including the NGC system, and serves over 100,000 customers worldwide. *Id.* Ex. N. Requiring Bio-Rad to stop selling the NGC product line for the pendency of this litigation would not put Bio-Rad out of business, and "[t]he notion that customers would cut [it] off from all sales of all products simply because [it was] unable to sell a relatively few types of [products] [would be] based upon nothing more than pure conjecture." *Canon*, 450 F. Supp. 2d at 256. Therefore, the balance of hardships weighs heavily in favor of issuing a preliminary injunction.

D. The Public Interest Favors An Injunction.

The public interest favors the issuance of a preliminary injunction in this case. First, "the public is best served by enforcing patents that are likely valid and infringed." *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006). Indeed, as the Federal Circuit has expressly acknowledged, "a preliminary injunction that enforces a valid patent against an infringer 'does no more than further public policy inherent in the patent laws designed to encourage useful inventions by rewarding the inventor with a limited period of market exclusivity.'" *Pfizer*, 429 F.3d at 1382 (citation omitted). *See also Canon*, 450 F. Supp. 2d at 257 ("There is a strong public interest in ensuring that valid patents are enforced. Such enforcement encourages and promotes useful inventions."). Because GE has established a likelihood of success on the merits, an injunction will in fact advance the public interest.

The ÄKTA avant and ÄKTA pure systems are sufficient to meet the needs of the preparative protein purification research community (Darby Decl. ¶ 29), and removing the NGC system from the market would not negatively impact researchers' abilities to complete their work. Additionally, GE has the manufacturing capacity to increase production of the ÄKTA avant and ÄKTA pure systems to meet all demand that currently is being met by the NGC system. *Id*. ¶ 29.

Furthermore, any disruption to researchers caused by a preliminary injunction will be significantly less now than at a later stage. For example, if Bio-Rad's infringement is allowed to continue, disruption will result in not only the researchers presently using the system, but in addition, all of the researchers who may be persuaded to begin using it between now and trial. *See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, No. 93-108, 1993 U.S. Dist. LEXIS 19959, at *31-32 (D. Del. July 16, 1993) (finding that "such disruption will be minimized by granting the preliminary injunction"); *Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, No. 94

CIV. 8634 (CBM), 1995 WL 512171 at *28 (S.D.N.Y. Aug. 28, 1995) ("[I]t is in the public interest to minimize disruption in customers selection and usage of products with the issuance of a preliminary injunction which precludes long-term utilization of and reliance on an allegedly infringing product."), vacated on other grounds, 77 F.3d 1364 (Fed. Cir. 1996).

V. CONCLUSION

For the foregoing reasons, GE respectfully request that the Court grant its present motion for a preliminary injunction in a form consistent with the [Proposed] Order filed herewith.

Dated: September 9, 2014

Respectfully submitted,

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